PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetergesic Multidose, 0.3mg/ml, solution for injection for dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1ml solution for injection contains:

Buprenorphine 0.3mg
As Buprenorphine hydrochloride 0.324mg
Chlorocresol 1.35mg

3. PACKAGE SIZE

10ml

4. TARGET SPECIES

Dogs and Cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intravenous, intramuscular.
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 28 days
Once opened, use by….

9. SPECIAL STORAGE PRECAUTIONS

Keep vial in outer carton in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

Vm 15052/5055

15. BATCH NUMBER

Lot:

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetergesic

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Buprenorphine 0.3mg
As Buprenorphine hydrochloride 0.324mg

3. BATCH NUMBER

Lot:

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 28 days
Once opened, use by….

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetergesic Multidose, 0.3mg/ml, solution for injection for dogs and cats

2. COMPOSITION

1 ml solution for injection contains:

Active substance:	
Buprenorphine	0.3 mg
as buprenorphine hydrochloride	0.324 mg
Excipient(s):	
Chlorocresol	1.35 mg
as antimicrobial preservative	

Clear, colourless solution for injection.

3. TARGET SPECIES

Dogs and Cats

4. INDICATIONS FOR USE

DOG
Post-operative analgesia.
Potentiation of the sedative effects of centrally-acting agents.

CAT
Post-operative analgesia

5. CONTRAINDICATIONS

Do not administer by the intrathecal or peridural route.
Do not use pre-operatively for Caesarian section.
Do not use cases of known hypersensitivity to the active substance or to any of the excipients.

6. SPECIAL WARNINGS

Special precautions for use in animals
Buprenorphine may cause respiratory depression and as with other opioid drugs, care should be taken when treating animals with impaired respiratory function or animals that are receiving drugs that can cause respiratory depression.
In case of renal, cardiac or hepatic dysfunction or shock, there may be greater risk associated with the use of the product. The benefit: risk assessment for using the product should be made by the attending veterinarian. Safety has not been fully evaluated in clinically compromised cats.

Buprenorphine should be used with caution in animals with impaired liver function, especially biliary tract disease, as the substance is metabolised by the liver and its intensity and duration of action may be affected in such animals.
The safety of buprenorphine has not been demonstrated in animals less than 7 weeks of age, therefore, use in such animals should be based on the risk: benefit assessment of the veterinarian.
Repeat administration earlier than the recommended repeat interval suggested in Section 34.9 is not recommended.
Long-term safety of buprenorphine in cats has not been investigated beyond 5 consecutive days of administration.
The effect of an opioid on head injury is dependent on the type and severity of the injury and the respiratory support supplied. The product should be used in accordance with the benefit:risk assessment of the attending veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands/affected area thoroughly after any accidental spillage.
As buprenorphine has opioid-like activity, care should be taken to avoid self-injection. In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Following eye contamination or skin contact, wash thoroughly with cold running water. Seek medical advice if irritation persists.

Pregnancy:
Laboratory studies in rats have not produced any evidence of a teratogenic effect. However, these studies have shown post-implantation losses and early foetal deaths. These may have resulted from a reduction in parental body condition during gestation and in post-natal care owing to sedation of the mothers.

As reproductive toxicity studies have not been conducted in the target species, use only according to the benefit/risk assessment by the responsible veterinarian.
The product should not be used pre-operatively in cases of Caesarean section, due to the risk of respiratory depression in the offspring periparturiently, and should only be used post-operatively with special care (see below).
Lactation:
Studies in lactating rats have shown that, after intramuscular administration of buprenorphine, concentrations of unchanged buprenorphine in the milk equalled or exceeded that in the plasma. As it is likely that buprenorphine will be excreted in the milk of other species, use is not recommended during lactation. Use only according to benefit: risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

Buprenorphine may cause some drowsiness, which may be potentiated by other centrally- acting agents, including tranquillisers, sedatives and hypnotics.
There is evidence in humans to indicate that therapeutic doses of buprenorphine do not reduce the analgesic efficacy of standard doses of an opioid agonist, and that when buprenorphine is employed within the normal therapeutic range, standard doses of opioid agonist may be administered before the effects of the former have

ended without compromising analgesia. However, it is recommended that buprenorphine is not used in conjunction with morphine or other opioid-type analgesics, e.g. etorphine, fentanyl, pethidine, methadone, papaveretum or butorphanol.
Buprenorphine has been used with acepromazine, alphaxalone/alphadalone, atropine, dexmedetomidine, halothane, isoflurane, ketamine, medetomidine, propofol, sevoflurane, thiopentone and xylazine. When used in combination with sedatives, depressive effects on heart rate and respiration may be augmented.

Overdose

When administered at overdose to dogs, buprenorphine may cause lethargy. At very high doses, bradycardia and miosis may be observed. In cases of overdosage, supportive measures should be instituted, and, if appropriate, naloxone or respiratory stimulants may be used.Naloxone may be of benefit in reversing reduced respiratory rate and respiratory stimulants such as doxapram are also effective in man. Because of the prolonged duration of effect of buprenorphine in comparison to such drugs, they may need to be administered repeatedly or by continuous infusion. Volunteer studies in man have indicated that opiate antagonists may not fully reverse the effects of buprenorphine. In toxicological studies of buprenorphine hydrochloride in dogs, biliary hyperplasia was observed after oral administration for one year at dose levels of 3.5mg/kg/day and above. Biliary hyperplasia was not observed following daily intramuscular injection of dose levels up to 2.5mg/kg/day for 3 months. This is well in excess of any clinical dose regimen in the dog.

Special precautions for the protection of the environment
Not applicable.

7. ADVERSE EVENTS

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypertension, Tachycardia
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain, Injection site irritation Vocalisation
Undetermined frequency (cannot be estimated from the available data):	Increased salivation Bradycardia Hypothermia, Dehydration
	Agitation Miosis Respiratory distress

Cats:

Common (1 to 10 animals / 100 animals treated):	Behavioural disorder NOS[1] (excessive purring), ~~Pacing[1]~~ Rubbing[1] Mydriasis[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain, Injection site irritation Vocalisation
Undetermined frequency (cannot be estimated from the available data):	Respiratory distress

[1] usually resolve within 24 hours.

When administered for analgesia sedation occurs rarely but may appear at higher dosages.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. National contact details: https://www.gov.uk/report-veterinary-medicine-problem

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Shake well before use.
An appropriately graduated syringe must be used to allow accurate dosing.

Administration: Dog – intramuscular or intravenous injection
Cat – intramuscular or intravenous injection

Species	1.1.1 Route of Administration	1.1.2 Post-Operative Analgesia	1.1.3 Potentiation of Sedation
Dog	Intramuscular or intravenous injection	10-20 ug per kg (0.3-0.6ml per 10kg). For further pain relief, repeat if necessary after 3- 4 hours with 10 ug per kg or 5-6 hours with 20 microgram per kg.	10-20 ug per kg (0.3-0.6ml per 10kg).

Cat	Intramuscular or intravenous injection	10 – 20 ug per kg (0.3 – 0.6ml per 10kg), repeated if necessary, once, after 1-2 hours.	---

9. ADVICE ON CORRECT ADMINISTRATION

While sedative effects are present by 15 minutes after administration, analgesic activity becomes apparent after approximately 30 minutes. To ensure that analgesia is present during surgery and immediately on recovery, the product should be administered preoperatively as part of premedication.
When administered for potentiation of sedation or as part of premedication, the dose of other centrally-acting agents, such as acepromazine or medetomidine, should be reduced. The reduction will depend on the degree of sedation required, the individual animal, the type of other agents included in premedication and how anaesthesia is to be induced and maintained. It may also be possible to reduce the amount of inhalational anaesthetic used.
Animals administered opioids possessing sedative and analgesic properties may show variable responses. Therefore, the response of individual animals should be monitored and subsequent doses should be adjusted accordingly. In some cases, repeat doses may fail to provide additional analgesia. In these cases, consideration should be given to using a suitable injectable NSAID.
An appropriately graduated syringe must be used to allow accurate dosing.

10. WITHDRAWAL PERIODS

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
Shake well before use.
Do not use this veterinary medicinal product after the expiry date stated on the carton and vial after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V – Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/5055

Box containing 1 glass vial of 10 ml

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing Authorisation Holder:
Ceva Animal Health
Ltd Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release
LABIANA LIFE SCIENCES, S.A.
C/ Venus, 26, Pol. Ind. Can Parellada, Terrassa, 08228 Barcelona, Spain

17. OTHER INFORMATION

Gavin Hall
Approved: 17 January 2025